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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,118	09/14/2004	Henrik Semb	034005-008	7902

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EXAMINER

TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/500,118	Applicant(s) SEMB ET AL.	
	Examiner Thaian N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Preliminary Amendment, filed 6/25/04, has been entered. Claims 1-56 are amended; claims 57-61 are newly added; claims 1-61 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, 35, 57-61, drawn to methods of obtaining a pluripotent human blastocyst-derived stem cell line, methods of propagating the stem cell line, the stem cell line, and a kit.

Group II, claim(s) 22-28, 36-49, 55, 56 drawn to methods of differentiating blastocyst-derived stem cells into insulin-producing cells, cells produced by the method

Group III, claim(s) 29, drawn to a preparation of differentiated cells for preventing or treating pathologies or diseases caused by tissue degeneration.

Group IV, claim(s) 30-32, 50-52 drawn to preparations of differentiated cells to be used for prevention or treatment of diseases of the pancreas.

Group V, claim(s) 33-34, 53, 54 drawn to preparations of differentiated cells in preventing or treating pathologies or diseases in the nervous system.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Art Unit: 1632

Unity of Invention between different categories of inventions will only be found to exist if specific combinations of inventions are present. Those combinations include:

- 1) A product and a special process of manufacture of said product
- 2) A product and a process of use of said product
- 3) A product, a special process of manufacture of said product, and a process of use of said product
- 4) A process and an apparatus specially designed to carry out said process
- 5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant invention.

37 CFR 1.475 (c) states that:

“If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.”

37 CFR 1.475 (d) states:

“If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).”

37 CFR 1.475(e) states:

“The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.”

In the instant case, the technical feature linking the groups is a blastocyst-derived stem cell line and the method of producing such a stem cell line. However, this technical feature fails to provide a contribution over the prior art, and thus fails to be a special technical feature. For example, Reubinoff *et al.* (cited on Applicants' IDS, filed 7/13/06) teaches stem cells produced from human blastocysts. Furthermore, methods of producing blastocyst-derived cell lines are known in the art. For example, Roach and McNeish (*Methods in Molecular Biology*, 185: Embryonic Stem Cells: Methods and Protocols. Edited by K. Turksen, Human Press, Inc., Totowa, NJ, 2002, pages 1-16) teach methods of isolation of murine ES cells, cited the art of Evans and Axelrod (References 1-2). Roach and McNeish show

Art Unit: 1632

that it was known in the prior art to produce stem cell lines by obtaining blastocyst stage embryos, culture the blastocysts on feeder cells, and then, once the embryos have attached, isolate the ICM. See page 4, # 3.4-3.5. Therefore, the technical feature linking the inventions of Groups I-V do not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, as stated above, multiple products (Groups I-V) and methods of making or using the products do not provide unity of invention. Finally, each of the methods that are listed in Groups I and II have materially separate protocol and require specific technical considerations.

The technical feature of Group I is considered to be the first named product (a blastocyst-derived stem cell line), methods of producing the stem cell line, and the first process of use of the stem cell line (propagating the stem cell line).

The technical feature of Group II is considered to be differentiation of a blastocyst-derived stem cell line into insulin-producing cells.

The technical feature of Group III is considered to be a preparation of differentiated cells for preventing or treating pathologies or diseases caused by tissue degeneration

The technical feature of Group IV is considered to be preparations of differentiated cells to be used for prevention or treatment of diseases of the pancreas.

The technical feature of Group V is considered to be preparations of differentiated cells in preventing or treating pathologies or diseases in the nervous system.

Accordingly, Groups I-V are not so linked by the same or a corresponding technical feature as to form a single, general inventive concept, and thus, it is determined that Groups I-V fail to have unity of invention.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Diseases of the Nervous System (as delineated in claim 34)

- i) multiple sclerosis
- ii) spinal chord injury
- iii) an encephalopathy
- iv) Parkinson's disease

- v) Huntington's disease
- vi) stroke
- vii) traumatic brain injury
- viii) hypoxia induced brain injury
- ix) ischemia induced brain injury
- x) hypoglycemic brain injury
- xi) a degenerative disorder of the nervous system
- xii) a brain tumor
- xiii) neuropathy in the peripheral nervous system

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species has a different etiology and different effect. Therefore they do not constitute a single, general inventive concept..

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Peter Paras, SPE of Art Unit 1632, at (571) 272-4517. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



THAIAN N. TON
PATENT EXAMINER